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MeVis
MEDICAL SOLUTIONS

510(k) Summary

Submitted By:	MeVis Medical Solutions AG Universitaetsallee 29 28359 Bremen, Germany
Establishment Name:	MeVis Medical Solutions AG
Establishment Registration Number:	Applied for and awaiting assignment by FDA
Contact Person:	Thomas E. Tynes President & CEO MeVis Medical Solutions, Inc. N27 W24075 Paul Court - Suite 100 Pewaukee, WI 53072 USA Phone: +1-262-691-9530 Fax: +1-262-691-9531
Date Prepared:	11/10/2011
Trade Name:	Visia™ Dynamic Review
Common Name:	Medical Image Processing Software
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Regulation Number:	892.1000
Class:	II
Panel:	Radiology
Product Code:	LNH

Device Description

Visia™ Dynamic Review is a software package intended for use in viewing and analyzing magnetic resonance imaging (MRI) studies. Visia™ Dynamic Review supports evaluation of dynamic MR data.

Visia™ Dynamic Review integrates within typical clinical workflow patterns through receiving and transferring medical images over a computer network. The software can be loaded on a standard off-the-shelf personal computer (PC) and can operate as a stand-alone workstation or in a distributed server-client configuration across a computer network.

Visia™ Dynamic Review automatically registers serial patient motion to minimize the impact of patient motion and visualizes different enhancement characteristics (parametric image maps). Furthermore, it performs other user-defined post-processing functions such as image subtractions; multi-planar reformats and maximum intensity projections.

The resulting information can be displayed in a variety of formats, including a parametric image overlaid onto the source image. Images can also be displayed based on physician preferences using configurable viewing options or hanging protocols.

Visia™ Dynamic Review provides the clinician with a broad set of viewing and analysis tools to annotate, measure, and output selected image views or user defined reports. Furthermore, Visia™ Dynamic Review can evaluate the uptake characteristics of segmented tissues.

Visia™ Dynamic Review also displays images from a number of other imaging modalities; however, these images must not be used for primary diagnostic interpretation.

Intended Use

Visia™ Dynamic Review is a software package intended for use in viewing and analyzing magnetic resonance imaging (MRI) studies. Visia™ Dynamic Review supports evaluation of dynamic MR data.

Visia™ Dynamic Review automatically registers serial patient motion to minimize the impact of patient motion and visualizes different enhancement characteristics (parametric image maps). Furthermore, it performs other user-defined post-processing functions such as image subtractions; multi-planar reformats and maximum intensity projections. The resulting information can be displayed in a variety of formats, including a parametric image overlaid onto the source image. Visia™ Dynamic Review can also be used to provide measurements for diameters, areas and volumes. Furthermore, Visia™ Dynamic Review can evaluate the uptake characteristics of segmented tissues.

Visia™ Dynamic Review also displays images from a number of other imaging modalities; however, these images must not be used for primary diagnostic interpretation.

When interpreted by a skilled physician, Visia™ Dynamic Review provides information that may be useful in diagnosis. Patient management decisions should not be made based solely on the results of Visia™ Dynamic Review analysis.

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Predicate Device Information

Product	Predicate Device Name	Predicate 510(k) Submission Reference
Visia™ Dynamic Review	Syngo BreVis	K090038

Safety and Effectiveness

The Visia™ Dynamic Review labeling contains instructions for use and necessary cautions, warnings and notes to provide for safe and effective use of the device. Risk Management is ensured via MeVis Medical Solution AG's Risk Management procedure, which is used to identify potential hazards. These potential hazards are controlled via software development and verification & validation testing.

Nonclinical Testing and Performance Information

The complete system configuration has been assessed and tested at the manufacturer's facility and has passed all in-house testing criteria. The Validation Test Plan was designed to evaluate all input functions, output functions, and actions performed by the software in each operational mode and followed the process documented in the Validation Test Plan.

Nonclinical testing results are provided in the 510(k). Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met.

Technological Characteristics

Visia™ Dynamic Review is a software device that does not contact the patient, nor does it control any life sustaining devices. Diagnosis is not performed by the software but by Radiologists, Clinicians and referring Physicians.

A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

The new device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The new device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices.

Conclusion

The 510(k) Pre-Market Notification for Visia™ Dynamic Review contains adequate information, data, and nonclinical test results to enable FDA – CDRH to determine substantial equivalence to the predicate device. MeVis Medical Solutions has determined that its device, Visia™ Dynamic Review, is substantially equivalent to the identified predicate device listed above. A comparison with the legally marketed predicate device indicates that it is substantially equivalent to this device, and that it does not raise any new safety or efficacy concerns. Nonclinical tests demonstrate that the device is safe, effective, and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MeVis Medical Solutions AG
% Mr. Thomas E. Tynes
President, CEO
MeVis Medical Solutions, Inc.
N27 W24075 Paul Court, Suite 100
PEWAUKEE WI 53072

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Re: K113337
Trade/Device Name: Visia™ Dynamic Review
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 10, 2011
Received: November 14, 2011

Dear Mr. Tynes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

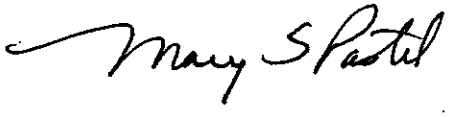
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K113337

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Indications for Use Statement

510(k) Number (if known): K113337

Device Name: Visia™ Dynamic Review

Indications for Use:

Visia™ Dynamic Review is a software package intended for use in viewing and analyzing magnetic resonance imaging (MRI) studies. Visia™ Dynamic Review supports evaluation of dynamic MR data.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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